Appendix XIV

CHAPTER 2.3.13.

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 2.3.13.1.

The recommendations in this chapter are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (*Bos taurus* and *B. indicus)* only.

Article 2.3.13.2.

The BSE status of the cattle population of a country or zone can only be determined on the basis of the following criteria:

1) **the outcome of a risk assessment identifying all potential factors for BSE occurrence and their historic perspective, in particular:**

   a) **the potential for introduction and recycling of the BSE agent through consumption by cattle of *meat-and-bone meal* or greaves of ruminant origin;**

   b) **importation of *meat-and-bone meal* or greaves potentially contaminated with a transmissible spongiform encephalopathy (TSE) or feedstuffs containing either;**

   c) **importation of animals or embryos/**[ova] **oocytes potentially infected with a TSE;**

   d) **epidemiological situation concerning all animal TSE in the country or zone;**

   e) **extent of knowledge of the population structure of cattle, sheep and goats in the country or zone;**

   f) **the origin and use of animal by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed** [production] **manufacture;**

2) **on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle to encourage reporting of all cases of neurological disease in adult cattle;**

3) **compulsory notification and investigation of all cattle showing clinical signs compatible with BSE;**

4) **a BSE surveillance and monitoring system with emphasis on risks identified in point 1) above, taking into account the guidelines in Appendix 3.8.3.; records of the number and results of investigations should be maintained for at least 7 years;**

5) **examination in an approved laboratory of brain or other tissues collected within the framework of the aforementioned surveillance system.**

Standards for diagnostic tests are described in the *Manual*.

Article 2.3.13.3.

BSE free country or zone

The cattle population of a country or zone may be considered free of BSE should the following conditions be met:

1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted and it has been demonstrated that appropriate measures have been taken for the relevant period of time to manage any risk identified;

2) either:

a) there has been no *case* of BSE; and either:

i) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years; or

ii) the criteria in point 3) of Article 2.3.13.2. have been complied with for at least 7 years and it has been demonstrated that for at least 8 years no *meat-and-bone meal* or greaves derived from ruminants have been fed to ruminants;

OR

b) all *cases* of BSE have been clearly demonstrated to originate directly from the importation of live cattle [or bovine embryos/ova], and the affected cattle as well as, if these are females, their last progeny born within 2 years prior to, or after, clinical onset of the disease, if alive in the country or zone, have been slaughtered and completely destroyed; and either:

i) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years; or

ii) the criteria in point 3) of Article 2.3.13.2. have been complied with for at least 7 years and it has been demonstrated that for at least 8 years no *meat-and-bone meal* or greaves derived from ruminants have been fed to ruminants;

OR

c) the last indigenous *case* of BSE was reported more than 7 years ago, the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years and the feeding of ruminants with *meat-and-bone meal* and greaves derived from ruminants has been banned and the ban has been effectively enforced for at least 8 years.

Article 2.3.13.4.

BSE provisionally free country or zone

The cattle population of a country or zone may be considered as provisionally free of BSE should the following conditions be met:

1) **a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted and it has been demonstrated that appropriate measures have been taken for the relevant period of time to manage any risk identified;**

2) either:

a) there has been no *case* of BSE; and either:

i) the criteria in points 2) to 5) of Article 2.3.13.2. are complied with, but have not been complied with for 7 years; or

ii) it has been demonstrated that for at least 8 years no *meat-and-bone meal* or greaves derived from ruminants have been fed to ruminants, but the criteria in point 3) of Article 2.3.13.2. have not been complied with for 7 years;

OR

b) all *cases* of BSE have been clearly demonstrated to originate directly from the importation of live cattle [or bovine embryos/ova]**, and the affected cattle as well as, if these are females, their last progeny born within 2 years prior to, or after, clinical onset of the disease, if alive in the country or zone, have been slaughtered and completely destroyed; and either:**

i) the criteria in points 2) to 5) of Article 2.3.13.2. are complied with, but have not been complied with for 7 years; or

ii) it has been demonstrated that for at least 8 years no *meat-and-bone meal* or greaves derived from ruminants have been fed to ruminants, but the criteria in point 3) of Article 2.3.13.2. have not been complied with for 7 years.

Article 2.3.13.5.

Country or zone with a minimal BSE risk

The cattle population of country or zone may be considered as presenting a minimal BSE risk should the country or zone comply with the following requirements:

1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted and it has been demonstrated that appropriate measures have been taken for the relevant period of time to manage any risk identified;

2) EITHER:

a) the last indigenous *case* of BSE was reported more than 7 years ago, the criteria in points 2) to 5) of Article 2.3.13.2. are complied with and the ban on feeding ruminants with *meat-and-bone meal* and greaves derived from ruminants is effectively enforced, but:

i) the criteria in points 2) to 5) of Article 2.3.13.2. have not been complied with for 7 years; or

ii) the ban on feeding ruminants with *meat-and-bone meal* and greaves derived from ruminants has not been effectively enforced for 8 years;

OR

b) the last indigenous *case* of BSE has been reported less than 7 years ago, and the BSE incidence rate, calculated on the basis of indigenous *cases*, has been less than one case per million during each of the last four consecutive 12-month periods within the cattle population over 24 months of age in the country or zone *(Note: For countries with a population of less than one million adult cattle, the maximum allowed incidence should be expressed in cattle-years.)*, and:

i) the ban on feeding ruminants with *meat-and-bone meal* and greaves derived from ruminants has been effectively enforced for at least 8 years;

ii) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 7 years;

iii) the affected cattle as well as:

- **if these are females, their last progeny born within 2 years prior to, or after, clinical onset of the disease,**
- **all cattle either born in the same herd as, and within 12 months of the birth of, the affected cattle or reared together with the affected cattle during the first year of their life, and, in both situations, which may have consumed the same potentially contaminated feed as that which the affected cattle consumed during the first year of their life,**

if alive in the country or zone, are slaughtered and completely destroyed.

Article 2.3.13.6.

Country or zone with a moderate BSE risk

The cattle population of a country or zone may be considered as presenting a moderate BSE risk if:

1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted, and the other criteria listed in Article 2.3.13.2. are complied with;

2) the BSE incidence rate, calculated over the past 12 months, has been:

a) greater than, or equal to, one indigenous *case* per million and less than, or equal to, one hundred cases per million within the cattle population over 24 months of age in the country or zone; or

b) less than one indigenous *case* per million for less than four consecutive 12-month periods *(Note: For countries with a population of less than one million adult cattle, the maximum allowed incidence should be expressed in cattle-years.)*;

3) the affected cattle as well as:

a) if these are females, their last progeny born within 2 years prior to, or after, clinical onset of the disease,

b) all cattle either born in the same herd as, and within 12 months of the birth of, the affected cattle or reared together with the affected cattle during the first year of their life, and, in both situations, which may have consumed the same potentially contaminated feed as that which the affected cattle consumed during the first year of their life,

if alive in the country or zone, are slaughtered and completely destroyed.

Countries and zones where the BSE incidence rate has been less than one indigenous *case* per million within the cattle population over 24 months of age during each of the last four consecutive 12-month periods, but where at least one of the other requirements to be considered as provisionally free from BSE or as presenting a minimal BSE risk is not complied with, shall be considered as countries or zones with a moderate BSE risk.

Article 2.3.13.7.

Country or zone with a high BSE risk

The cattle population of a country or zone may be considered as presenting a high BSE risk if:

1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted, the other criteria listed in Article 2.3.13.2. are complied with, and the BSE incidence rate, calculated over the past 12 months, has been greater than one hundred cases per million within the cattle population over 24 months of age in the country or zone; or

2) the BSE incidence rate, calculated over the past 12 months, has been greater than, or equal to, one case per million and less than, or equal to, one hundred cases per million within the cattle population over 24 months of age in the country or zone, but at least one of the other requirements to be considered as presenting a moderate BSE risk is not complied with.

Article 2.3.13.8.

Regardless of the BSE status of the *exporting country*, *Veterinary Administrations* should authorise without restriction the import or transit through their territory of the following *commodities*:

1) milk and milk products;

2) semen and embryos;

3) protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;

4) dicalcium phosphate (with no trace of protein or fat);

5) hides and skins;

6) gelatin and collagen prepared exclusively from hides and skins.

Article 2.3.13.9.

When importing from a BSE free country or zone, *Veterinary Administrations* should require:

for all *commodities* from cattle not listed in Article 2.3.13.8.

the presentation of an *international veterinary certificate* attesting that the country or zone complies with the conditions in Article 2.3.13.3. to be considered as free of BSE.

Article 2.3.13.10.

When importing from a BSE provisionally free country or zone, *Veterinary Administrations* should require:

for cattle

the presentation of an *international veterinary certificate* attesting that:

1) **the country or zone complies with the conditions in Article 2.3.13.4. to be considered as provisionally free of BSE;**

2) **cattle selected for export are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect females.**

Article 2.3.13.11.

When importing from a country or zone with a minimal BSE risk, *Veterinary Administrations* should require:

for cattle

the presentation of an *international veterinary certificate* attesting that:

1) the country or zone complies with the conditions in Article 2.3.13.5. to be considered as presenting a minimal BSE risk;

2) cattle selected for export:

a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect or confirmed females;

b) were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and greaves derived from ruminants has been effectively enforced.

Article 2.3.13.12.

When importing from a country or zone with a moderate BSE risk, *Veterinary Administrations* should require:

for cattle

the presentation of an *international veterinary certificate* attesting that:

1) the country or zone complies with the conditions in Article 2.3.13.6. to be considered as presenting a moderate BSE risk;

2) the feeding of ruminants with *meat-and-bone meal* and greaves derived from ruminants has been banned and the ban has been effectively enforced;

3) cattle selected for export:

a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect or confirmed females;

b) were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and greaves derived from ruminants has been effectively enforced.

Article 2.3.13.13.

When importing from a country or zone with a high BSE risk, *Veterinary Administrations* should require:

for cattle

the presentation of an *international animal health certificate* attesting that:

1) **the country or zone complies with the conditions in Article 2.3.13.7. to be considered as presenting a high BSE risk;**

2) the feeding of ruminants with *meat-and-bone meal* and greaves derived from ruminants has been banned and the ban has been effectively enforced;

3) the affected cattle as well as:

a) if these are females, their last progeny born within 2 years prior to, or after, clinical onset of the disease,

b) all cattle either born in the same herd as, and within 12 months of the birth of, the affected cattle or reared together with the affected cattle during the first year of their life, and, in both situations, which may have consumed the same potentially contaminated feed as that which the affected cattle consumed during the first year of their life,

if alive in the country or zone, are slaughtered and completely destroyed;

4) cattle selected for export:

a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect or confirmed females;

b) were born at least 2 years after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and greaves derived from ruminants was effectively enforced.

Article 2.3.13.14.

When importing from a BSE provisionally free country or zone, *Veterinary Administrations* should require:

for *fresh meat* (bone-in or deboned) and *meat products* from cattle

the presentation of an *international veterinary certificate* attesting that:

1) the country or zone complies with the conditions in Article 2.3.13.4. to be considered as provisionally free of BSE;

2) ante-mortem inspection is carried out on all cattle from which the meat or *meat products* destined for export originate.

Article 2.3.13.15.

When importing from a country or zone with a minimal BSE risk, *Veterinary Administrations* should require:

for *fresh meat* (bone-in or deboned) and *meat products* from cattle

the presentation of an *international veterinary certificate* attesting that:

1) the country or zone complies with the conditions in Article 2.3.13.5. to be considered as presenting a minimal BSE risk;

2) ante-mortem inspection is carried out on all cattle from which the meat or *meat products* destined for export originate;

3) **[cattle from which the meat or *meat products* destined for export originate were not slaughtered using pneumatic stunning by injection of compressed air or gas into the cranial cavity or pithing (laceration, after stunning, of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity)]**cattle from which the meat or *meat products* destined for export originate were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process (laceration, after stunning, of central nervous tissue by means of an elongated rod-shaped instrument introduced;

4) the *fresh meat* and *meat products* destined for export have neither been contaminated by, nor contain either brain, eyes, spinal cord or mechanically separated meat from skull and vertebral column from cattle over 30 months of age.

Article 2.3.13.16.

When importing from a country or zone with a moderate BSE risk, *Veterinary Administrations* should require:

for *fresh meat* (bone-in or deboned) and *meat products* from cattle

the presentation of an *international veterinary certificate* attesting that:

1) the country or zone complies with the conditions in Article 2.3.13.6. to be considered as presenting a moderate BSE risk;

2) the feeding of ruminants with *meat-and-bone meal* and greaves derived from ruminants has been banned and the ban has been effectively enforced;

3) ante-mortem inspection is carried out on all bovines;

4) [cattle from which the meat or *meat products* destined for export originate were not slaughtered using pneumatic stunning by injection of compressed air or gas into the cranial cavity or pithing]cattle from which the meat or *meat products* destined for export originate were not subjected to a stunning process, prior to slaughter**, with a device injecting compressed air or gas into the cranial cavity or to a pithing process;**

5) the *fresh meat* and *meat products* destined for export have neither been contaminated by, nor contain, brain, eyes, spinal cord, distal ileum or mechanically separated meat from skull and vertebral column from cattle over 6 months of age.

Article 2.3.13.17.

When importing from a country or zone with a high BSE risk, *Veterinary Administrations* should require:

for *fresh meat* and *meat products* from cattle

the presentation of an *international veterinary certificate* attesting that:

1) the country or zone complies with the conditions in Article 2.3.13.7. to be considered as presenting a high BSE risk;

2) the meat destined for export, if obtained from animals over 9 months of age, has been deboned and has neither been contaminated by, nor contains the tissues listed in point 1) of Article 2.3.13.19. nor nervous and lymphatic tissues exposed during a deboning process;

3) the *meat products* destined for export are derived from deboned meat and have neither been contaminated by, nor contain the tissues listed in point 1) of Article 2.3.13.19. nor

nervous and lymphatic tissues exposed during a deboning process, nor mechanically separated meat from skull and vertebral column of bovine animals;

4) **a system is in operation enabling the *fresh meat* and *meat products* destined for export to be traced back to the *establishments* from which they are derived;**

5) **ante-mortem inspection is carried out on all bovines;**

6) the cattle from which the meat or *meat products* destined for export originate:

a) were identified by a permanent identification system enabling them to be traced back to the dam and herd of origin;

b) are not the progeny of BSE suspect or confirmed females; and either:

i) were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and greaves derived from ruminants has been effectively enforced; or

ii) were born, raised and had remained in herds in which no *case* of BSE had been confirmed for at least 7 years;

c) [were not slaughtered using pneumatic stunning by injection of compressed air or gas into the cranial cavity or pithing]were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process;

7) the feeding of ruminants with *meat-and-bone meal* and greaves derived from ruminants has been banned and the ban has been effectively enforced;

8) the affected cattle as well as:

a) if these are females, their last progeny born within 2 years prior to, or after, clinical onset of the disease,

b) all cattle either born in the same herd as, and within 12 months of the birth of, the affected cattle or reared together with the affected cattle during the first year of their life, and, in both situations, which may have consumed the same potentially contaminated feed as that which the affected cattle consumed during the first year of their life,

if alive in the country or zone, are slaughtered and completely destroyed.

[Article 2.3.13.17.

When importing from a BSE provisionally free country or zone, *Veterinary Administrations* should require:

for bovine embryos/ova

the presentation of an *international veterinary certificate* attesting that:

1) the country or zone complies with the conditions in Article 2.3.13.3. to be considered as provisionally free of BSE;

2) the embryos/ova were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.3.13.18.

When importing from a country or zone with a minimal BSE risk, *Veterinary Administrations* should require:

for bovine embryos/ova

the presentation of an *international veterinary certificate* attesting that:

1) the country or zone complies with the conditions in Article 2.3.13.4. to be considered as presenting a minimal BSE risk;

2) embryos/ova destined for export are derived from females which:

a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin;

b) are not the progeny of BSE suspect or confirmed females;

c) were not suspected of being affected by BSE at the time of e

mbryo collection;

3) the embryos/ova were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.3.13.19.

When importing from a country or zone with a moderate BSE risk, *Veterinary Administrations* should require:

for bovine embryos/ova

the presentation of an *international veterinary certificate* attesting that:

1) the country or zone complies with the conditions in Article 2.3.13.5. to be considered as presenting a moderate BSE risk;

2) the feeding of ruminants with *meat-and-bone meal* and greaves derived from ruminants has been banned and the ban has been effectively enforced;

3) embryos/ova destined for export are derived from females which:

a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not the progeny of BSE suspect or confirmed females;

b) are not affected with BSE;

c) were not suspected of being affected of BSE at the time of embryo collection; and

d) either were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and greaves derived from ruminants was effectively enforced; or

e) were born, raised and had remained in herds in which no *case* of BSE had been confirmed for at least 7 years;

4) the embryos/ova were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.

Article 2.3.13.20.

When importing from a country or zone with a high BSE risk, *Veterinary Administrations* should require:

for bovine embryos/ova

the presentation of an *international veterinary certificate* attesting that:

1) the country or zone complies with the conditions in Article 2.3.13.6. to be considered as presenting a high BSE risk;

2) the feeding of ruminants with *meat-and-bone meal* and greaves derived from ruminants has been banned and the ban has been effectively enforced;

3) the affected cattle, as well as, if these are females, their last progeny born within 2 years prior to, or after, clinical onset of the disease, if alive in the country or zone, are slaughtered and completely destroyed;

4) embryos/ova destined for export are derived from females which:

a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not the progeny of BSE suspect or confirmed females;

b) are not affected with BSE;

c) were not suspected of being affected by BSE at the time of embryo collection; and

d) either were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and greaves derived from ruminants was effectively enforced; or

e) were born, raised and had remained in herds in which no *case* of BSE had been confirmed for at least 7 years, and which contain only cattle born on the farm or coming from a herd of equal status;

5) the embryos/ova were collected, processed and stored in conformity with the provisions of Appendix 3.3.1.]

Article 2.3.13.**[21]**18.

Ruminant-derived *meat-and-bone meal* or greaves, or any feedstuffs containing such products, which originate from countries with a high BSE risk should not be traded between countries.

Ruminant-derived *meat-and-bone meal* or greaves, or any feedstuffs containing such products, which originate from countries or zones not free from BSE should not be traded between countries for use in ruminant feed. For other uses, the imported *meat-and-bone meal* or greaves should have been processed in plants which are approved and regularly controlled by the relevant *Veterinary Administration* following validation that each plant can achieve the processing parameters described in Appendix 3.6.3. In addition, if originating from a country or zone with a minimal BSE risk or from a country or zone with a moderate BSE risk, ruminant-derived *meat-and-bone meal* or greaves, or any feedstuffs containing such products, should comply with the provisions in point 2) of Article 2.3.13.19.

Article 2.3.13.**[22]**19.

1) **The following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, tonsils, thymus, spleen, intestines, dorsal root ganglia, trigeminal ganglia, skull and vertebral column, and protein products derived therefrom, from cattle over 6 months of age originating from countries with a high BSE risk. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.**

2) **The following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices:**

   a) **brains, eyes, spinal cord, distal ileum, skull, vertebral column and protein products derived therefrom, from cattle, originating from a country or zone with a moderate BSE risk, that were at the time of slaughter aged over 6 months;**

   b) **brains, eyes and spinal cord, skull, vertebral column and protein products derived therefrom, from cattle, originating from a country or zone with a minimal BSE risk has been reported, that were at the time of slaughter aged over 30 months.**

   Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using the commodities listed in points a) and b) above should also not be traded.

Article 2.3.13.**[23]**20.

***Veterinary Administrations* of *importing countries* should require:**

for gelatin and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that the bones came from:

1) **a BSE free or provisionally free country or zone, or from a country or zone with a minimal BSE risk; or**

2) a country or zone with a moderate BSE risk; and

a) skulls and vertebrae (excluding tail vertebrae) have been excluded;

b) the bones have been subjected to a process which includes all the following steps:

i) pressure washing (degreasing),

ii) acid demineralisation,

iii) prolonged alkaline treatment,

iv) filtration,

v) sterilisation at ³ 138°C for a minimum of 4 seconds,

or to an equivalent process in terms of infectivity reduction.

Article 2.3.13.**[24]**21.

***Veterinary Administrations* of *importing countries* should require:**

for tallow (other than protein-free tallow as defined in Article 2.3.13.8.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that it originates from:

1) a BSE free or provisionally free country or zone; or

2) a country or zone with a minimal BSE risk, and

a) if prepared by fat melting, it originates from cattle which have been subjected to an ante-mortem inspection for BSE with favourable results and has not been prepared using the tissues listed in point 2)b) of Article 2.3.13.19.;

b) if prepared by rendering, (under study); or

3) a country or zone with a moderate BSE risk; and

a) if prepared by fat melting, it originates from cattle which have been subjected to an ante-mortem inspection for BSE with favourable results and has not been prepared using the tissues listed in point 2)a) of Article 2.3.13.19.;

b) if prepared by defatting of bones:

i) skulls and vertebral columns from cattle over 6 months of age have been excluded; or

ii) it has been processed using a method that reduces the infectivity by at least 5 $\log_{10} LD_{50}$/g (processes under study);

c) if prepared by rendering, (under study).

Article 2.3.13.**[25]**22.

***Veterinary Administrations* of *importing countries* should require:**

for tallow derivatives (other than those made from protein-free tallow as defined in Article 2.3.13.8.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that:

1) they originate from a BSE free or provisionally free country or zone, or from a country or zone with a minimal BSE risk;

OR

2) they have been produced by hydrolysis, saponification or transesterification using high temperature and pressure.

Article 2.3.13.**[26]**23.

Careful selection of source materials is the best way to ensure maximum safety of ingredients or reagents of bovine origin used in the manufacture of medicinal products.

Countries wishing to import bovine materials for such purposes should therefore consider the following factors:

1) the BSE status of the country and herd(s) where the animals have been kept, as determined under the provisions of Articles 2.3.13.2. to 2.3.13.7.;

2) the age of the donor animals;

3) the tissues required and whether or not they will be pooled samples or derived from a single animal.

Additional factors may be considered in assessing the risk from BSE, including:

4) precautions to avoid contamination during collection of tissues;

5) the process to which the material will be subjected during manufacture;

6) the amount of material to be administered;

7) the route of administration.

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APPENDIX 3.8.3.

SURVEILLANCE AND MONITORING SYSTEMS FOR BOVINE SPONGIFORM ENCEPHALOPATHY

Article 3.8.3.1.

Introduction

The surveillance strategy applied for bovine spongiform encephalopathy (BSE) should be determined by, and commensurate with the outcome of the risk assessment referred to in Article 2.3.13.2. Surveillance and risk assessment are part of an iterative process and inform each other.

Surveillance for BSE has at least two goals: one is to determine whether BSE is present in the country, and the other, once the disease has been detected, is to monitor the evolution of the epizootic, direct control measures and monitor their effectiveness.

A surveillance strategy may need to combine several methods of investigation.

Surveillance for BSE requires laboratory examination of samples in accordance with the methods described in the *Manual*.

For surveillance purposes, testing a part of the population is consistent with Chapter 1.3.5. on surveillance and monitoring of animal health. Recommended strategies for selecting the part of the population for testing are described below.

Article 3.8.3.2.

Examination of cattle displaying clinical signs compatible with BSE

Cattle affected by illnesses that are refractory to treatment, and displaying progressive behavioural changes such as excitability, persistent kicking when milked, changes in herd hierarchical status, hesitation at doors, gates and barriers, as well as those displaying progressive neurological signs without signs of infectious illness are candidates for examination. Since BSE causes no pathognomonic clinical signs, all countries with cattle populations will observe individual animals with compatible clinical signs. Surveillance should primarily focus on cattle over 30 months of age, but younger cattle should not be ignored.

Table 1 indicates the minimum number of clinical cases that should be subjected to diagnostic tests according to the total cattle population over 30 months of age. As this sampling is not random, the numbers indicated in this table are a subjective interpretation rather than a strict statistical deduction.

Table 1. ***Minimum number of annual investigations of animals showing clinical signs compatible with BSE required for effective surveillance according to the total cattle population over 30 months of age***

Total cattle population over 30 months of age	Minimum number of samples to examine
500,000	50
700,000	69
1,000,000	99
2,500,000	195
5,000,000	300
7,000,000	336
10,000,000	367
20,000,000	409
30,000,000	425
40,000,000	433

Article 3.8.3.3.

Examination of targeted cattle not displaying clinical signs compatible with BSE

Cattle that have died or have been killed for reasons other than routine slaughter (including 'fallen' stock and emergency slaughter) should be examined. Surveillance needs to focus on animals over 30 months of age.

Article 3.8.3.4.

Examination of cattle subject to normal slaughter

In countries not free from BSE, sampling at routine slaughter is a means of monitoring the progress of the epizootic and the efficacy of control measures applied, because it offers continuous access to a cattle population of known class, age structure and geographical origin.

Exclusive dependence on random sampling from normal cattle is not recommended, unless the number of samples examined annually is statistically sufficient to detect a disease prevalence of 1 in 1,000,000.

Article 3.8.3.5.

Within each of the above sub-populations, countries may wish to target cattle identifiable as imported from countries or zones not free from BSE, cattle which have consumed potentially contaminated feedstuffs from countries or zones not free from BSE, offspring of BSE affected cows and cattle which have consumed feedstuffs potentially contaminated with other TSE agents.